IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

Angela Benson, Plaintiff, v. Boston Scientific Corporation, Defendant.	)	Case No. 6:18-cv-02456-DCC **OPINION AND ORDER**

This matter is before the Court on [27] Plaintiff's Motion to Exclude Certain Testimony of Steven Spiegelberg, Ph.D.; [28] Plaintiff's Motion to Exclude Certain Testimony of Peter Rosenblatt, M.D.; [29] Plaintiff's Motion to Exclude Certain Opinions and Testimony of Steven E. Swift, M.D.; [30] Plaintiff's Motion to Exclude Certain Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D.; and [31] Plaintiff's Motion to Exclude Certain Opinions and Testimony of Steven R. Little, Ph.D. The matters have been fully briefed and are ripe for review.

BACKGROUND

This case arises out of injuries allegedly sustained by the Plaintiff as a result of the implantation of the Obtryx Transobturator Midurethral Sling System (Obtryx), which was marketed by Defendant and implanted by Dr. Matthew L. Smith in Greenville, South Carolina on September 13, 2010. ECF No. 1. On March 24, 2017, Plaintiff direct filed a Short Form Complaint in the *In Re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation MDL No. 2326.* ECF No. 1. Plaintiff alleges causes of action for negligence, strict liability, breach of express warranty, and breach of implied warranty. *Id.* at 4–5. Plaintiff's pretrial matters were consolidated with many other cases and handled

by the Honorable Joseph R. Goodwin, United States District Judge for the Southern District of West Virginia ("the MDL Judge").

On May 29 and 30, 2018, the MDL Judge issued orders on a large number of pretrial motions in limine. ECF Nos. 46–63. On August 22, 2018, the MDL Judge issued an order, which granted Defendant's Motion for Summary Judgment as to one of Plaintiff's strict liability claims and denied the Motion as to Plaintiff's remaining claims. ECF No. 69. On August 23, 2018, the MDL Judge issued an order transferring Plaintiff's case to the District of South Carolina for trial.[1] ECF No. 70. Accordingly, the case was transferred on September 6, 2018. The Court has reviewed the docket sheet that was transmitted from the MDL proceedings, and it appears there are five motions pending resolution. The Court has attempted to ascertain the status of Plaintiff's representation by contacting Plaintiff's counsel from the MDL, but as of the date of this Order, no counsel has appeared on Plaintiff's behalf, nor has Plaintiff's MDL counsel provided the Court with any meaningful information about when local counsel will appear.[2] Accordingly, the Court will decide the pending Motions on the briefings without oral argument.

LEGAL STANDARD

The admission of expert testimony in federal courts is governed by Federal Rule of Evidence 702, which permits the court to allow testimony from a witness qualified as an expert if: "(a) the expert's scientific, technical, or other specialized knowledge will help

[1] Plaintiff's Short Form Complaint and the transfer order both improperly refer to this district as the Southern District of South Carolina. ECF Nos. 1, 70.

[2] *See* Local Civ. R. 83.I.04 (D.S.C.) ("Litigants in civil and criminal actions, except for parties appearing *pro se*, must be represented by at least one member of the bar of this court who shall sign each pleading, motion, discovery procedure, or other document served or filed in this court.").

the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." "In *Daubert*, the [Supreme] Court announced five factors that may be used in assessing the relevancy and reliability of expert testimony: (1) whether the particular scientific theory 'can be (and has been) tested'; (2) whether the theory 'has been subjected to peer review and publication'; (3) the 'known or potential rate of error'; (4) the 'existence and maintenance of standards controlling the technique's operation'; and (5) whether the technique has achieved 'general acceptance' in the relevant scientific or expert community." *United States v. Crisp*, 324 F.3d 261, 266–67 (4th Cir. 2003) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. at 579, 593–94 (1993)).

The inquiry envisioned by Rule 702 is a flexible one, and "[i]ts overarching subject is the scientific validity and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission." *Daubert*, 509 U.S. at 594–95. "In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful; the particular factors will depend upon the unique circumstances of the expert testimony involved." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (1999) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149–52 (4th Cir. 1999)). "The court, however, should be conscious of two guiding, and sometimes competing, principles." *Id.* "On the one hand, the court should be mindful that Rule 702 was intended to liberalize the introduction of relevant expert evidence." *Id.* (citing *Cavallo v. Star Enter.*, 100 F.3d 1150, 1158–59 (4th Cir. 1996)). "On the other hand, the court must recognize that due to the

difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'" *Id.* (quoting *Daubert*, 509 U.S. at 595). "[G]iven the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *Id.* (citing *United States v. Dorsey*, 45 F.3d 809, 815–16 (4th Cir. 1995)).

DISCUSSION

I. Steven Spiegelberg, Ph.D.

On January 11, 2018, Plaintiff moved to exclude: (1) Dr. Spiegelberg's general causation opinions regarding the position statements of medical organizations; (2) Dr. Spiegelberg's state of mind, intent and scientific validity opinions related to Material Safety Data Sheets ("MSDS"); (3) Dr. Spiegelberg's opinions on any matters related to the FDA clearance process (or Defendant's compliance with it); (4) Dr. Spiegelberg's opinions regarding the presence of black specks in Defendant's mesh; (5) Dr. Spiegelberg's opinions regarding individual explanted mesh; and (6) Dr. Spiegelberg's general causation opinions based on his Fourier Transform Infrared Spectroscopy ("FTIR") and Electron Dispersive Spectroscopy ("EDS") testing. ECF No. 27. On February 1, 2018, Defendant filed a Response in Opposition. ECF No. 36. On February 8, 2018, Plaintiff filed a Reply. ECF No. 41.

On May 30, 2018, the MDL Judge issued an Order on Plaintiff's Motion, addressing each of the issues raised by Plaintiff as to Dr. Spiegelberg's proposed testimony. ECF No. 58. Specifically, the Order: (1) denied as moot as to the position statement opinions; (2) denied as to the MSDS opinions; (3) granted in part and denied in part as to the FDA clearance process opinions, prohibiting Dr. Spiegelberg from opining about the FDA

510(k) clearance process but permitting him to opine on International Organization for Standardization standards; (4) denied as to the opinions about black specks; (5) denied as to the opinions about individual explant testing; and (6) denied as to the opinions based on FTIR and EDS testing. *See id.* at 10 (noting that the ruling applied to Plaintiff's case). However, on June 7, 2018, the MDL Judge stamped, "This motion is **RESERVED**. It is so **ORDERED.**" on Plaintiff's Motion and filed that document on the docket. ECF No. 64. In light of this apparent inconsistency, it appears the June 7, 2018, Order reserving ruling on Plaintiff's Motion was a scrivener's error, as Plaintiff's Motion had already been granted in part, denied in part, and denied as moot in part. In the event the parties can demonstrate that there remains a live dispute with respect to this Motion, the parties may refile an appropriate motion within the deadlines prescribed by the forthcoming scheduling order. Accordingly, the Motion is dismissed as moot with leave to refile.

II. Peter Rosenblatt, M.D.

On January 11, 2018, Plaintiff moved to exclude: (1) Dr. Rosenblatt's opinions regarding tenderness to palpation and/or reports of dyspareunia; (2) Dr. Rosenblatt's opinions regarding degradation of mesh; (3) Dr. Rosenblatt's opinions regarding tissue integration and pore size; (4) Dr. Rosenblatt's opinion that myofascial pain is a well-recognized cause of post-operative pain after pelvic surgery; (5) Dr. Rosenblatt's opinions regarding the adequacy of the Directions for Use ("DFU"); (6) Dr. Rosenblatt's opinions related to the MSDS; (7) Dr. Rosenblatt's opinion that the vagina is a sterile environment, suitable for the placement of synthetic mesh; (8) Dr. Rosenblatt's opinions related to FDA approval; and (9) Dr. Rosenblatt's opinions related to various position statements. ECF

No. 28. On February 1, 2018, Defendant filed a Response in Opposition. ECF No. 39. On February 8, 2018, Plaintiff filed a Reply. ECF No. 45.

On May 30, 2018, the MDL Judge issued an Order on Plaintiff's Motion, which granted in part, denied in part, and reserved in part. ECF No. 59. Specifically, the Order: (1) denied as to the degradation opinions; (2) granted as to the tissue integration and pore size opinions; (3) reserved ruling on the myofascial pain opinions until trial; (4) denied as to the adequacy of the DFU; (5) reserved ruling until further testimony may be offered and evaluated firsthand at trial as to the MSDS opinions; (6) reserved ruling until further testimony may be offered and evaluated firsthand at trial as to the sterile environment opinion; (7) granted as to the FDA approval opinions; and (8) reserved ruling on the position statement opinions. *See id.* at 10 (noting that the ruling applied to Plaintiff's case). However, on June 7, 2018, the MDL Judge stamped, "This motion is **RESERVED**. It is so **ORDERED.**" on Plaintiff's Motion and filed this document on the docket. ECF No. 65. In light of this apparent inconsistency, it appears the June 7, 2018, Order reserving ruling on Plaintiff's Motion was a scrivener's error, as Plaintiff's Motion had already been ruled on in large part.

The May 30, 2018, Order does, however, fail to address Plaintiff's claim that Dr. Rosenblatt should be precluded from offering testimony related to tenderness to palpation and/or reports of dyspareunia by patients. ECF No. 28 at 4. Specifically, Dr. Rosenblatt notes in his expert report, "[i]n over 10 years of placing TVT and TOT slings, [he] ha[s] had extremely low rates of de novo dyspareunia with both slings." ECF No. 28-1 at 18. Prior to making this statement, Dr. Rosenblatt discusses, at length, a variety of medical studies relevant to his opinion. *Id.* at 17–19. This review of the medical literature,

combined with Dr. Rosenblatt's clinical experience, certainly provides a sufficient basis for the admission of his expert testimony. While Plaintiff may disagree with Dr. Rosenblatt's opinions, they are free to cross examine him at trial. Accordingly, Plaintiff's Motion, as it relates to the palpation and dyspareunia opinions, is denied. As to the remainder of the claims, in the event the parties can demonstrate that there remains a live dispute with respect to the Motion, the parties may refile an appropriate motion within the deadlines prescribed by the forthcoming scheduling order. Accordingly, the Motion is dismissed as moot with leave to refile in part and denied in part.

III. Steven E. Swift, M.D.

Plaintiff also filed a Motion to Exclude Certain Opinions and Testimony of Steven E. Swift, M.D. ECF No. 29. Prior to addressing Plaintiff's specific objections, the Court will summarize Dr. Swift's expert report as it relates to Plaintiff. *See* ECF No. 29-1.

Dr. Swift is the Director of the Division of Female Pelvic Medicine and Reconstructive Surgery and a tenured Professor in the Department of Obstetrics and Gynecology at the Medical University of South Carolina. ECF No. 29-1 at 2. He is Board Certified in General Obstetrics and Gynecology and in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery. *Id.* His "clinical practice is focused on treatment of women with pelvic floor disorders. The majority of women [he] treat[s] suffer from urinary incontinence and/or pelvic organ prolapse." *Id.* In his clinical practice, he has extensively treated these conditions utilizing both mesh and non-mesh procedures. *Id.*

Dr. Swift details the various types of incontinence and how they are treated. *Id.* at 2–5. One method of treatment that he commonly uses is implanting a mid-urethral sling, including the Obtryx. *Id.* at 5. When implanting a mid-urethral sling, such as an Obtryx,

Dr. Swift claims that his "complication rate is low and consistent with complications reported in the clinical literature." *Id.* Dr. Swift then discusses clinical literature that he believes demonstrates the safety and efficacy of mid-urethral slings, including Obtryx. *Id.* at 6–9. After the clinical literature review, Dr. Swift opines that mid-urethral slings are the standard of care in treatment of stress urinary incontinence, stating:

> I have not seen evidence of polypropylene degradation, systemic infection, mesh shrinkage/contracture, or other unexpected adverse outcomes following placement of an Obtryx sling. Polypropylene is known to be a durable material, as it has been used in the body for years—well before its incorporation into midurethral slings. In fact, the vast majority of surgeons agree that "polypropylene material is safe and effective as a surgical implant."

Id. at 9–10 (quoting AUGS/SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (Issued January 2014)). Dr. Swift also notes that he has "reviewed the Directions For Use (DFU) for the Obtryx and it is [his] opinion as a physician using these products that Boston Scientific adequately warned of many of these potential risks so that [he] and other physicians can fully and accurately counsel patients." *Id.* at 6.

Turning to Plaintiff's specific case, Dr. Swift outlines the numerous complications Plaintiff suffered after the implantation of the Obtryx. Based upon his review of the medical evidence, Dr. Swift opines that Plaintiff's bladder spasms, urinary retention, and urinary incontinence were not caused by any defect in the Obtryx sling. *Id.* Instead, Dr. Swift contends that Plaintiff's symptoms are "idiopathic" and "due to some form of bladder outlet obstruction that was (and is) relieved by an Alpha adrenergic blocker suggesting it is due to bladder outlet spasm." *Id.* at 12. In short, Dr. Swift opined that "the benefits of the Obtryx midurethral sling outweighed the possible risks to [Plaintiff]." *Id.*

Plaintiff seeks to exclude a variety of Dr. Swift's opinions in her Motion, claiming that Dr. Swift's opinions are not specific to this Plaintiff and are not based on reliable facts and data. For purposes of organization, the Court will generally address Plaintiff's arguments under the same headings used in the Motion.

A. Similarity of Cure Rates of Mesh and Non-Mesh Surgeries

Plaintiff summarily argues that Dr. Swift's opinion that "clinical literature established that treatment of stress urinary incontinence with a macroporous, monofilament polypropylene mesh mid-urethral sling had cure rates similar or superior to non-mesh incontinence surgeries" should be excluded because Dr. Swift fails to reference any clinical literature that supports this opinion. ECF No. 29-1 at 3–4. Defendant responds that Dr. Swift cites a variety of studies to support his opinion in addition to his "extensive training, education, and clinical experience." ECF No. 38 at 4.

Daubert dictates that the Court must focus on the principles and methodology employed by the expert, not the conclusion reached. Here, Dr. Swift is a qualified urogynecologist with substantial experience with mesh and non-mesh treatment of stress urinary incontinence ("SUI"). His opinion that the efficacy of mesh based treatment is similar to, or better than, non-mesh based treatment is based not only on his extensive experience, but also on the numerous studies cited in his expert report. Accordingly, the Court concludes that Dr. Swift may testify about the efficacy of mesh surgeries compared to non-mesh surgeries. Therefore, Plaintiff's Motion is **DENIED** as to this issue.

B. Gold Standard of Care

Next, Plaintiff seeks to exclude Dr. Swift's "opinion that polypropylene mid-urethral slings are the gold standard of care for treatment of SUI." ECF No. 29-1 at 4. As detailed

above, however, Dr. Swift offers this opinion based on his extensive clinical experience and a detailed review of medical literature that is outlined in his expert report. The Court concludes that Dr. Swift adequately explains the principles and methodology leading to his opinion. Therefore, Plaintiff's Motion is **DENIED** as to this issue.

C. Safety and Effectiveness

Plaintiff next seeks to exclude Dr. Swift's opinion that mid-urethral slings "are safe and effective for the treatment of stress urinary incontinence." *Id.* at 29-1 at 5. As set forth above in Sections A and B, Dr. Swift bases this opinion on his extensive experience teaching, implanting, and researching mid-urethral slings as well as an extensive review of the relevant literature. *See* ECF No. 38 (noting Dr. Swift's reliance on "sixteen (16) publications on the safety and efficacy of polypropylene mid-urethral slings, including two studies specifically looking at the Obtryx"). The principles and methodology utilized by Dr. Swift are sufficient under *Daubert*. Therefore, Plaintiff's Motion is **DENIED** as to this issue.

D. Adequacy of Warnings

Plaintiff next seeks to exclude Dr. Swift's opinion that Defendant adequately warned about the risks of the Obtryx. Dr. Swift's report states, "[i]t was well known in the medical community by 2004 (much earlier, actually) that midurethral slings carried a risk of mesh erosion, pain, dyspareunia, bleeding, inflammation, infection, abscess, urinary dysfunction, urinary retention, recurrent or worsened SUI, detrusor instability and injury to blood vessels, nerves, the bladder, and/or bowel. I reviewed the Directions for Use (DFU) for the Obtryx and it is my opinion as a physician using these products that Boston Scientific adequately warned of many of these potential risks so that I and other

physicians can fully and accurately counsel patients." ECF No. 29-1 at 6. Plaintiff contends "Dr. Swift does not possess the requisite expertise to testify to the adequacy of the Directions for Use (DFU) for the Obtryx device." ECF No. 29 at 6.

The MDL Judge has addressed a similar issue in several prior cases. For example, in *Mathison v. Boston Sci. Corp.*, the MDL Judge discussed the propriety of a urologist, Dr. Lonny S. Green, testifying about the adequacy of Defendant's warnings:

> First, the plaintiffs argue that Dr. Green is not qualified to offer opinions on the Obtryx DFU because he has never written a DFU and could not describe the general requirements for a DFU during his deposition. In response, [Defendant] contends that Dr. Green does not need to be a warnings or regulatory expert "to offer competent, helpful testimony on the subject of whether Boston Scientific adequately warned of the risks and complications the plaintiff alleges."
>
> Author and astronomer, Carl Sagan, popularized the aphorism, "Absence of evidence is not evidence of absence." Sagan's aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false. Instead, there is often insufficient investigation and information to come to a conclusive determination. Sagan's musings are relevant here because the plaintiffs have challenged the defendant's attempt to offer experts seeking to opine on the adequacy of product warnings. In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, [Defendant's] experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while [Defendant's] experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included risks he has observed in his own practice.

> In his expert report, Dr. Green discusses the risks of pelvic surgery and states that "[a]ll of the aforementioned potential complications are adequately warned of in the [DFU] for the Obtryx sling." Dr. Green fails to address the significance of complications he has not seen in his practice, and which are not warned of in the DFU. In his deposition, Dr. Green admits he has never drafted a DFU for a medical device or pharmaceutical. Although Dr. Green indicates he has "expertise" in the process of writing patient handouts warning against drug complications, his experience appears to be limited to his review and distribution of these handouts, rather than contribution to the drafting. Accordingly, I **FIND** that Dr. Green is not qualified to opine on the adequacy of product warnings, and therefore, his opinions related to the Obtryx DFU are **EXCLUDED.**

No. 2:13-cv-05851, at *27 (S.D.W. Va. May 6, 2015) (internal citations omitted).

Here, Defendant acknowledges the MDL Judge has ruled against its position in prior cases. *See* ECF No. 38 at 5 (acknowledging the MDL Judge's ruling in *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501 (S.D.W. Va. 2014). Defendant contends the case at bar is different because Dr. Swift is offering opinions about risks he has observed in practice and are identified in Defendant's DFU. The Court disagrees and finds the reasoning of the MDL Judge in *Mathison* and *Tyree* persuasive. Dr. Swift apparently has no experience in developing product warnings or other areas that would enable him to reliably opine about the adequacy of Defendant's warnings/DFU. Accordingly, Plaintiff's Motion is **GRANTED** as to this issue, with the caveat that Dr. Swift can, of course, testify about the risks he has seen in practice and whether Defendant warned him (and the patients) of those risks. He may not, however, offer any testimony about the ultimate adequacy of the DFU/warnings.

E. Surgical Technique

Plaintiff also seeks to exclude Dr. Swift's opinion that "[m]esh erosion is not a result of any defect in the mesh, but is rather typically caused by surgeon technique, generally in the form of excess tension placed on the sling or dissection in the wrong surgical plane."

ECF No. 29-1 at 7. The Court agrees. Dr. Swift's expert report is devoid of any research about problems with surgical technique or the frequency with which mesh erosion occurs due to different surgical techniques. Instead, Dr. Swift merely offers an alternative hypothesis to that proposed by the Plaintiff in this case. That alternative hypothesis appears to be based solely on Dr. Swift's subjective opinion and experience. Accordingly, Plaintiff's Motion is **GRANTED** as to this issue.

F. Adequacy of DFU

Plaintiff again asks the Court to exclude Dr. Swift's opinion that the DFU adequately warns physicians of the potential risks and complications of the Obtryx. The Court has decided this issue in Section D above, incorporates its analysis herein, and **GRANTS** Plaintiff's Motion on this issue.

G. Surgeon's Reliance on MSDS for Raw Materials

Next, Plaintiff seeks to exclude Dr. Swift's opinion that physicians do not rely on the MSDS of raw materials used in medical supplies. ECF No. 29-1 at 7. The Court agrees that this opinion is not based on reliable facts and data. Dr. Swift explains that he has never consulted a MSDS "for the purpose of evaluating the safety and efficacy of a medical device for treating, advising, or counseling a patient." *Id*. He further states that he did not learn about MSDS in medical school, residency, or other professional educational settings, nor does he teach his students to rely on MSDS. *Id.* Again, these subjective observations are not sufficient to satisfy the requirements of *Daubert*. Dr. Swift has not offered any reliable, peer-reviewed data to support his opinion. Additionally, this opinion is merely a means to bolster Dr. Swift's improper opinion about the adequacy of

Defendant's warnings and DFU. Accordingly, Plaintiff's Motion is **GRANTED** as to this issue.

H. Physical Properties of Polypropylene Mesh

Plaintiff also seeks to exclude Dr. Swift's opinions regarding the physical properties of polypropylene mesh, including mesh degradation, shrinkage/contracture, and systemic infection. Dr. Swift opined that he has "not seen evidence of polypropylene degradation, systemic infection, mesh shrinkage/contracture, or other unexpected adverse outcomes following placement of an Obtryx sling." ECF No. 29 at 9. Dr. Swift then noted the polypropylene is "a durable material" and discussed some of the physical properties of polypropylene mesh that make it safe as a surgical implant. *Id.* There is no question that Dr. Swift is an accomplished urogynecologist, who has extensive experience treating patients with SUI using mesh and reviewing the relevant scientific literature. The MDL Judge has previously allowed physicians with similar qualifications to opine about polypropylene mesh's physical properties. *See Tyree*, 54 F. Supp. 3d at 501 (discussing prior rulings allowing physicians to testify about the physical properties of polypropylene mesh). The Court agrees with the MDL Judge and finds that Dr. Swift is qualified to opine about the physical properties of polypropylene mesh but only as they relate to Plaintiff's injuries. *See id.* Accordingly, Plaintiff's Motion is **GRANTED IN PART** and **DENIED IN PART** on this issue.

I. Position Statements

Finally, Plaintiff seeks to exclude Dr. Swift's opinions regarding the safety, efficacy, or acceptance of Defendant's products, which are based on "position statements" of various medical organizations. Specifically, Dr. Swift relies on a joint position statement

in support of the safety and efficiency of mid-urethral slings issued by the American Urogynecologic Society ("AUGS") and the Society of Urodynamic, Female Pelvic Medicine & Urogenital Reconstruction, as well as quotes from position statements issued by AUGS, the American Urological Association ("AUA") and the Food and Drug Administration. ECF No. 29-1 at 9.

In prior orders, the MDL Judge has held that position statements are not expert opinions as the proposed expert "is not using his 'scientific, technical, or other specialized knowledge' in making these statements." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 731–32 (S.D.W. Va. 2014) (quoting Fed. R. Evid. 702); *see also in re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation*, MDL No. 2326, 2018 WL 2440261, at *4 (S.D.W. Va. May 29, 2018) ("Finally, plaintiffs seek to exclude Dr. Rosenblatt's references to organizational position statements issued by the American Urogynecologic Society. As I indicated previously during these MDLs, position statements are not expert opinions."). The Court agrees with the MDL Judge and finds that Dr. Swift's references to position statements do not qualify as expert opinions under Federal Rule of Evidence 702. Accordingly, Plaintiff's Motion is **DENIED** as to this issue.

IV. Stephen Badylak, D.V.M., Ph.D., M.D.

On January 11, 2018, Plaintiff moved to exclude: (1) Dr. Badylak's state of mind or intent opinions related to MSDS; (2) Dr. Badylak's opinions relating to the risk/benefit analysis or safety and efficacy of the devices; (3) Dr. Badylak's opinions relating to the correlation (or lack of correlation) of microscopic findings with clinical symptoms; and (4) Dr. Badylak's opinions related to oxidative degradation. ECF No. 30. On February 1,

2018, Defendant filed a Response in Opposition. ECF No. 37. On February 8, 2018, Plaintiff filed a Reply. ECF No. 42.

On May 30, 2018, the MDL Judge denied Plaintiff's Motion, addressing each of the issues raised by Plaintiff as to Dr. Badylak's proposed testimony. ECF No. 49 at 1 (denying Plaintiff's Motion), 8 (noting that the ruling applied to Plaintiff's case). However, on June 7, 2018, the MDL Judge stamped, "This motion is **RESERVED**. It is so **ORDERED.**" on Plaintiff's Motion and filed this document on the docket. ECF No. 67. In light of this apparent inconsistency, it appears the June 7, 2018, Order reserving ruling on Plaintiff's Motion was a scrivener's error, as Plaintiff's Motion had already been denied. In the event the parties can demonstrate that there remains a live dispute with respect to this Motion, the parties may refile an appropriate motion within the deadlines prescribed by the forthcoming scheduling order. Accordingly, the Motion is dismissed as moot with leave to refile.

V. Steven R. Little, Ph.D

On January 11, 2018, Plaintiff moved to exclude Dr. Little's opinions on oxidative degradation and Dr. Little's state of mind or intent opinions related to MSDS. ECF No. 31. On February 1, 2018, Defendant filed a Response in Opposition. ECF No. 40. On February 8, 2018, Plaintiff filed a Reply. ECF No. 43.

On May 30, 2018, the MDL Judge granted Plaintiff's Motion in part and denied Plaintiff's Motion in part, addressing each of the issues raised in the Motion. ECF No. 52 at 8. Specifically, the Order denied Plaintiff's Motion as to Dr. Little's opinion that polypropylene mesh does not degrade *in vivo* and granted Plaintiff's Motion as to Dr. Little's opinions related to the MSDS. However, on June 7, 2018, the MDL Judge

stamped, "This motion is **RESERVED**. It is so **ORDERED.**" on Plaintiff's Motion and filed this document on the docket. ECF No. 66. In light of this apparent inconsistency, it appears the June 7, 2018, Order reserving ruling on Plaintiff's Motion was a scrivener's error, as Plaintiff's Motion had already been denied in part and granted in part. In the event the parties can demonstrate that there remains a live dispute with respect to this Motion, the parties may refile an appropriate motion within the deadlines prescribed by the forthcoming scheduling order. Accordingly, the Motion is dismissed as moot with leave to refile.

CONCLUSION

This is a complex case, involving a number of experts. The Court expects this case to be tried in an orderly and expedient manner. In an earlier order in this MDL litigation, the MDL Judge forewarned, "[t]he danger—and to my jaded eye, the near certainty—of the admission of 'junk science' looms large in this mass litigation." *Flores-Banda v. Boston Sci. Corp.*, No. 2:13-cv-04434, 2016 WL 2939522 (S.D.W. Va. May 19, 2016). Accordingly, the Court expects all parties to strictly abide by the pretrial orders issued in this case.

For the foregoing reasons, the Court **DISMISSES AS MOOT WITH LEAVE TO REFILE** [27] Plaintiff's Motion to Exclude Certain Testimony of Steven Spiegelberg, Ph.D.; [30] Plaintiff's Motion to Exclude Certain Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D.; and [31] Plaintiff's Motion to Exclude Certain Opinions and Testimony of Steven R. Little, Ph.D. The Court further **DISMISSES AS MOOT WITH LEAVE TO REFILE IN PART** and **DENIES IN PART** [28] Plaintiff's Motion to Exclude Certain Testimony of Peter Rosenblatt, M.D. Finally, The Court **GRANTS IN PART** and **DENIES**

IN PART [29] Plaintiff's Motion to Exclude Certain Opinions and Testimony of Steven E. Swift, M.D.

As Plaintiff is still unrepresented in this action, this case will remain with a United States Magistrate Judge for further pretrial proceedings pursuant to 28 U.S.C. § 636(b) and Local Civil R. 73.02(B)(e).

IT IS SO ORDERED.

s/Donald C. Coggins, Jr.
United States District Judge

September 25, 2018
Spartanburg, South Carolina